

REMARKS

Status of Claims.

Claims 18, 28, 29 and 39 have been amended to recite that the compositions of the invention are "devoid of a polycarbophil", support for which is found in the specification at page 5.

New claims 48-51 are directed to compositions wherein chondroitin sulfate (or sodium hyaluronate) and propylene glycol are present in the specific weight ratios stated in the Examples.

Accordingly, claims 18-51 are under consideration.

Rejection under 35 U.S.C. 103(a).

Claims 18-47 of record were rejected as being obvious over U.S. Patent No. 5,801,199 ("Greve *et al.*") in view of US Pub. No. 2003/0060486 ("Jacob *et al.*").

The Greve *et al.* reference is directed to the combination of an α -sympathomimetic compound such as xylometazoline or oxymetazoline with a pantothenic compound for treating rhinitis. Greve *et al.* at Example 6 discloses this combination in a polyacrylate gel. However, as applicants have noted previously, the Greve *et al.* reference lacks a teaching of a mucopolysaccharide as defined by applicants, let alone a composition comprising the combination of a mucopolysaccharide and polypropylene glycol.

The secondary reference, Jacob *et al.*, on the other hand, describes certain "viscous and mucoadhesive" polymers as being useful in the treatment of mucosal diseases with or without an active pharmaceutical ingredient. The Examiner relies on the Jacob *et al.* disclosure of "[a] linear or cross-linked polymer polyanionic or polycationic polymer" including, *inter alia*, dextran sulfate, dermatan sulfate and hyaluronic acid (Par. 69), together with the mention elsewhere in the reference of polyethylene glycol, as the basis for finding applicants' claims prima facie obvious.

However, Jacob *et al.* must be read in its entirety -- not simply for its broad-brush recitations but also for the preferences and qualifications expressed in it. The clear, stated preference of Jacob and co-workers is for a *synthetic polymer* based on acrylic acid and methacrylic acid, such as Carbopol, Noveon or Eudragit L-100, and especially a mixture of Carbopol and Noveon (Pars. 69, 80), rather than any of the mucopolysaccharides claimed by applicants. A worker in the art reading the Jacob *et al.* specification and examples prior to preparing nasal compositions having mucoadhesive properties would be lead to use a synthetic polymer such as Carbopol, and in particular combinations of such polymers, rather than the mucopolysaccharides of applicants' claims. Applicants' current amendment of claims 18, 28, 29

and 39 to provide that the compositions of the invention are "devoid of polycarbophil" further distinguishes over the cited art.

With regard to the polyethylene glycol component of applicants' claims, its mention in Jacob et al. is, to begin with, in the context of a broad-brush disclosure of 7 possible classes and types of humectants known in the art, and even more importantly, solely in connection with "provid[ing] a pleasant mouth-feel in oral applications" (Par. 783). It would be a misreading of Jacob et al. to find a suggestion to use propylene glycol to improve the properties of a nasal composition, as applicants are claiming, as opposed to a composition for oral administration.

Thus, Greve et al. in itself is insufficient to establish a prima facie obviousness rejection because it does not teach the mucopolysaccharides required by applicants' claims. Alternatively, Jacob et al. duly mentions various mucoadhesive polymers available to workers in the art such as dextran sulfate or dermatan sulfate, but also unambiguously states a preference for polyacrylic acid hydrogels, indicating that the "most effective formulation" tested by Jacob and co-workers consisted of a mixture of Carbopol 971 and Noveon AA1. Furthermore, Jacob et al. simply fails to supply a teaching of polyethylene glycol for nasal administration; and accordingly is missing any sort of teaching or motivation to combine a mucoadhesive polymer with polyethylene glycol, as claimed, to achieve improved nasal compositions.

There is nothing in the cited references to suggest the improvements in moisturizing properties, hydration, and resistance to contamination, provided by applicants' claimed combination of selected mucopolysaccharide polymers with propylene glycol.

Applicants continue to be of the view that the Examiner has relied on hindsight reconstruction to pick and choose from the cited art only so much as will support his position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." In re Wesslau, 353 F.2d 238, 241, 53 C.C.P.A. 746 (C.C.P.A. 1965).


Accordingly, the obviousness rejection of record of claims 18-47 over Greve et al. in view of Jacob et al. should be withdrawn; and early allowance of claims 18-51 is respectfully solicited.

Fees.

Applicants request that any additional claim fees, or other fees necessitated by this paper, be charged to Deposit Account No. 50-4395 in the name of Novartis Consumer Health, Inc.

Respectfully submitted,

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